UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

JACQUELINE CLAY, individually and on behalf of all others similarly situated,

Plaintiff,

v.

THE PROCTER & GAMBLE COMPANY,

Defendant.

No. 1:21-cv-11133-JPC-GWG

ORAL ARGUMENT REQUESTED

DEFENDANT THE PROCTER & GAMBLE COMPANY'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT

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INTRODUCTION

This lawsuit seeks to challenge the labeling of DayQuil, an over-the-counter medication that has been safely used to treat cold and cough symptoms since 1976. Plaintiff alleges that DayQuil is misleadingly labeled as "non-drowsy" because one of its active ingredients—dextromethorphan—can supposedly cause drowsiness in consumers.

The Complaint fails to mention, however, that the Food and Drug Administration ("FDA") has already considered this exact issue and reached the opposite conclusion. The FDA strictly regulates the statements that manufacturers can make on labels for over-the-counter medications like DayQuil. For many cough medicines, the FDA requires a warning that the products "may cause drowsiness" or "may cause marked drowsiness." But the FDA expressly declined to require a similar warning for products that contain dextromethorphan. That was because "[t]he agency is not aware of data demonstrating that the antitussive ingredient[] . . . dextromethorphan . . . require[s] a drowsiness warning." 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983).

The FDA's conclusion means that all of Plaintiff's claims should be dismissed as preempted by federal law. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), all state law claims that impose requirements that are "different from," "in addition to," or "otherwise not identical" with federal labeling requirements are expressly preempted. 21 U.S.C. § 379r(a). Here, the FDA declined to require manufacturers to disclose "drowsiness" as a side effect of dextromethorphan and FDA regulations do not prohibit manufacturers from labeling products containing dextromethorphan as "non-drowsy." Plaintiff's claims are therefore preempted because they seek to use state law to impose requirements that are different from those imposed by the FDA. Courts have addressed virtually identical claims to those asserted by Plaintiff and found them to be preempted by the FDCA. *See Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 36–37 (2d Cir. 2020); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014).

The Complaint should also be dismissed because it fails to plausibly allege that The Procter & Gamble Company ("P&G") made a false or misleading statement. Plaintiff asserts that DayQuil is falsely labeled as "non-drowsy" because dextromethorphan causes drowsiness, but the sources cited in the Complaint say no such thing. To use just one example, the main study cited by Plaintiff concludes that "*somnolence was reported for a low percentage of patients*" taking dextromethorphan. Moreover, even if Plaintiff had plausibly alleged that dextromethorphan in *isolation* could cause drowsiness, that allegation has nothing to do with whether DayQuil *as a whole* has that effect on consumers.

Plaintiff's claims should be dismissed for independent reasons, as well. The claim for violations of seven "State Consumer Protection Acts" fails because Plaintiff makes no attempt to allege the elements of those claims or demonstrate that, as a New York resident, she has the right to sue under the laws of states other than New York. The claims under New York's General Business Law ("GBL") fail because Plaintiff cannot allege that she paid any premium to purchase "non-drowsy" DayQuil, which is the exact same price as NyQuil. The claim for breach of express warranty should be dismissed because Plaintiff did not provide timely pre-suit notice of that claim. And Plaintiff cannot plead a Magnuson-Moss Warranty Act ("MMWA") claim because (i) the phrase "non-drowsy" is not an actionable warranty and (ii) Plaintiff cannot satisfy the $25 amount-in-controversy threshold.

For these and the additional reasons set forth below, the Complaint should be dismissed.

BACKGROUND

I. The FDA Monograph Process For Over-The-Counter Drugs.

The FDA regulates most over-the-counter medications through a monograph process. A monograph is a set of regulations that describe the conditions under which a category of drugs may be marketed without a prescription. *See* 21 C.F.R. § 330.1; *Nat. Res. Def. Council, Inc. v. U.S.*

Food & Drug Admin., 710 F.3d 71, 75 (2d Cir. 2013) (describing the monograph process). A monograph is a "like a recipe" for each category of over-the-counter drugs: it "sets out the FDA-approved active ingredients for a given therapeutic class of OTC drugs" and specifies acceptable doses, formulations, and labeling for covered drugs. *Id.*; *see also* 21 C.F.R. § 330.1. An over-the-counter drug that complies with a monograph "is generally recognized as safe and effective and is not misbranded." 21 C.F.R. § 330.1.[1]

The FDA's monograph process is rigorous. A monograph is developed only after the FDA has appointed an advisory panel of independent experts, which "review[s] all available data" and reports its "conclusions and recommendations" to the FDA "with respect to the safety and effectiveness of the drugs." 21 C.F.R. § 330.10(a). Based on the panel's recommendations, the FDA publishes a proposed monograph for public comment, and then proceeds to publish a "tentative final monograph" for further public comment. *Id.* § 310.10(a)(7). "After reviewing [any] objections, the entire administrative record including all new data and information and comments, and considering the arguments made at any oral hearing," the FDA publishes a final monograph "establishing conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded." *Id.* § 310.10(a)(9).

II. Federal Requirements For Dextromethorphan.

The FDA began the monograph process for over-the-counter cold and cough medications in 1972. *See* 41 Fed. Reg. 38,312, 38,314 (Sept. 9, 1976). The agency appointed an advisory panel of experts to evaluate the safety and efficacy of active ingredients used in cold and cough medications, including dextromethorphan. *Id.* The panel, which included physicians and

[1] In March 2020, Congress replaced the rulemaking process for over-the-counter drug monographs with an administrative order process, which makes it easier for the FDA to issue and revise monographs. *See* Pub. L. No. 116-136, § 3851, 134 Stat. 281, 435 (2020).

pharmacologists, thoroughly reviewed literature and data concerning the safety and efficacy of various ingredients. *Id.* at 38,319–418. The panel held more than 20 multi-day working meetings and considered presentations from more than 40 witnesses. *Id.* at 38,314.

After publishing proposed and tentative final monographs and receiving public comments, the FDA published its final monograph for over-the-counter drugs used to relieve coughs, which are known as "antitussives." 52 Fed. Reg. 30,042, 30,055–56 (Aug. 12, 1987) (codified at 21 C.F.R. § 341.74). The final monograph for antitussives contains detailed and comprehensive labeling requirements for products that contain dextromethorphan. These requirements include an approved list of indications, warnings, and directions. *See* 21 C.F.R. §§ 341.74(b)(3)(vi)–(vii), (c)(4)(v)–(vii), (d)(1)(iii).

Significantly, the FDA monograph does not require manufacturers to disclose that drowsiness is a side effect of dextromethorphan. Nor does the monograph prohibit manufacturers from labeling dextromethorphan as "non-drowsy." Instead, the FDA concluded during the monograph process that "dextromethorphan is probably the safest antitussive presently available." 48 Fed. Reg. at 48,581. The FDA also specifically rejected claims that dextromethorphan may cause drowsiness, noting that "[t]he agency is not aware of data demonstrating that the antitussive ingredients codeine and dextromethorphan could be classified as Category I nighttime sleep-aids or that they require a drowsiness warning." *Id.* at 48,589.

By contrast, the final monograph requires products containing a different antitussive—diphenhydramine—to disclose on labels that they "[m]ay cause marked drowsiness." 21 C.F.R. §§ 341.74(c)(4)(viii)–(ix). Similarly, the FDA has issued other final monographs for over-the-counter medications that require a drowsiness warning. These warnings take two forms: medications that cause a lower degree of drowsiness must include a "may cause drowsiness"

warning, while medications that cause a greater degree of drowsiness must include a "may cause *marked* drowsiness" warning. *See id.* § 341.72(c)(3) (requiring "[m]ay cause drowsiness" disclosure for several antihistamines); *id.* § 341.72(c)(4) (requiring "[m]ay cause marked drowsiness" disclosure for diphenhydramine or doxylamine); *id.* § 341.85(c)(4) (requiring "[m]ay cause marked drowsiness" disclosure when an antihistamine is combined with an oral antitussive).

III. Plaintiff's Allegations.

Although the FDA final monograph does not require manufacturers to disclose drowsiness as a side effect of dextromethorphan, Plaintiff alleges that DayQuil products are misleading to consumers because they "do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." Compl. ¶ 13; *see also id.* ¶ 22. Plaintiff contends that "drowsiness" is a common side effect of dextromethorphan, and it is therefore "misleading to label a product 'Non-Drowsy' . . . if drowsiness is a known side effect of one of its active ingredients." *Id.* ¶¶ 16, 20.

Plaintiff's allegations about the supposed drowsiness effect of dextromethorphan appear only in paragraphs 17 through 19 of the Complaint. There, Plaintiff relies on a 1997 study that purportedly finds that drowsiness is an effect of dextromethorphan (Compl. ¶ 17), but the study in fact concludes that "somnolence was reported for a low percentage of patients" taking dextromethorphan. *See* Declaration of Henry Liu ("Liu Decl."), Ex. A at 2. Plaintiff also asserts that the FDA's adverse event report database lists "sedation" as a side effect of products containing dextromethorphan (Compl. ¶ 18), but she ignores the FDA's warning that a reported event "does not mean that the drug or biologic caused the adverse event."[2] Finally, Plaintiff points to a

[2] FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard.

guidance document from the Federal Aviation Administration ("FAA") prohibiting pilots from taking a "combination" of "cough medications" and "sedating antihistamines" (Compl. ¶ 19), but that guidance is wholly consistent with FDA regulations. *See* 21 C.F.R. § 341.85(c)(4) (requiring "may cause marked drowsiness" disclosure on label when an antihistamine is combined with antitussive like dextromethorphan).

Plaintiff nevertheless asserts that P&G "misled . . . consumers about the effects of the Non-Drowsy DayQuil Products." Compl. ¶ 3. On that basis, she asserts class action claims (1) under the consumer protection acts of six states and the District of Columbia (*id.* ¶¶ 40–47), (2) under New York's GBL §§ 349 and 350 (*id.* ¶¶ 48–64), (3) for breach of express warranty (*id.* ¶¶ 65–71), and (4) for violations of the MMWA (*id.* ¶¶ 72–80). Plaintiff seeks, among other relief, recovery of the "premium" she paid to purchase DayQuil and an injunction prohibiting P&G from labeling DayQuil products as "Non-Drowsy." *Id.* ¶¶ 28, 82.

PROCEDURAL STANDARD

"To survive a motion to dismiss," a complaint must "'state a claim to relief that is plausible on its face,'" *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230 (2d Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)), "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Instead, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. This standard is intended to expose pleading deficiencies "at the point of minimum expenditure of time and money by the parties and the court." *Id.* at 558 (quotations omitted).

ARGUMENT

I. All of Plaintiff's Claims Are Preempted By Federal Law.

The FDCA expressly preempts all state law claims that impose requirements that are "different from," "in addition to," or "otherwise not identical" with federal labeling requirements. 21 U.S.C. § 379r(a). Here, the FDA has issued a final monograph for antitussives that sets forth the specific disclosures that manufacturers must make on labels for products that contain dextromethorphan. *Supra* at 3–4. The final monograph does not require P&G to disclose "drowsiness" as a side effect of dextromethorphan or prohibit P&G from labeling products containing dextromethorphan as "non-drowsy." Plaintiff's claims are therefore preempted.

A. The FDCA expressly preempts state law claims that impose labeling requirements different from a final monograph.

The Supremacy Clause of the U.S. Constitution establishes that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Free v. Bland*, 369 U.S. 663, 666 (1962). Where a federal statute contains an express preemption clause, courts "do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Puerto Rico v. Franklin California Tax-Free Tr.*, 579 U.S. 115, 125 (2016) (quotations omitted).

In 1997, Congress responded to the lack of uniformity resulting from 50 different state standards for over-the-counter drug labels by enacting the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296. The Act added an express preemption clause to the FDCA titled "National Uniformity for Nonprescription Drugs." 21 U.S.C. § 379r. Section 379r declares that "no State or political subdivision of a State may establish or continue in effect any requirement" that relates to an over-the-counter drug that is

"different from or in addition to, or that is otherwise not identical with" federal law. *Id.* A state requirement is "not identical to" federal law if it "directly or indirectly" imposes labeling requirements that are "not imposed by or contained in the applicable [federal] provision (including any implementing regulation)" or that "[d]iffer from those specifically imposed or contained in the applicable provision." 21 C.F.R. § 100.1(c)(4) (interpreting similar preemption provision for food labeling). The "state imposed requirements" that are subject to express preemption under Section 379r include false advertising, warranty, and other common law claims. *See Bimont v. Unilever U.S., Inc.*, 2015 WL 5256988, at *9 (S.D.N.Y. Sept. 9, 2015).

Courts in this Circuit have given Section 379r sweeping preemptive effect. Under Section 379r, "preemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is *also* appropriate when a state law prohibits labeling that is *not prohibited* under federal law." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014). "The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*." *Id.*; *see also Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 35–36 (2d Cir. 2020) (holding that analogous express preemption provision for cosmetics preempts "*any* state law that provides for labeling requirements that are not *exactly the same* as those set forth in the FDCA and its regulations"); *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008) ("Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements.").

Preemption under Section 379r is especially appropriate where state law is used to challenge label statements that are allowed under a final monograph. "With respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to private litigants—or judges—

to decide what is 'false or misleading.' It is up to the FDA." *Bowling*, 65 F. Supp. 3d at 377. Thus, where a final monograph sets forth the specific disclosures that must be on a label for an over-the-counter drug, "the state requirements are not permitted unless they are *identical* to federal standards" set forth in the monograph. *Id.* at 375 (quotations omitted); *see also Harris v. Topco Assocs., LLC*, 538 F. Supp. 3d 826, 833 (N.D. Ill. 2021) (state claims preempted if they seek to "impose additional obligations . . . not imposed by" a monograph); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1290 (C.D. Cal. 2008) (state law claims challenging cold and cough medications preempted because they impose different requirements from the monograph).

B. Plaintiff's claims are barred by the final monograph for antitussives.

Plaintiff alleges that the statement "non-drowsy" on the labels for DayQuil is false and misleading under state law because "drowsiness is a common side effect" of dextromethorphan. Compl. ¶ 2. She therefore seeks to hold P&G liable because DayQuil products "do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." *Id.* ¶ 13. Section 379r preempts Plaintiff's claims because the FDA declined to require the disclosure of drowsiness as a side effect for dextromethorphan or prohibit the labeling of products containing dextromethorphan as "non-drowsy."

The FDA's final monograph for antitussives sets forth the specific indications, warnings, and directions that must appear on a product containing dextromethorphan. *See* 21 C.F.R. §§ 341.74(b)(3)(vi)–(vii), (c)(4)(v)–(vii), (d)(1)(iii). Notably, the monograph does not require manufacturers to include a drowsiness warning on labels for over-the-counter medications containing dextromethorphan. The FDA reached this conclusion because "[t]he agency is not aware of data demonstrating that the antitussive ingredients codeine and dextromethorphan could be classified as Category I nighttime sleep-aids *or that they require a drowsiness warning*." 48 Fed. Reg. at 48,589 (emphasis added). Elsewhere, the FDA has embraced studies showing that

the incidence of drowsiness in participants taking dextromethorphan was *lower* than participants taking a placebo. 44 Fed. Reg. 51,512, 51,526, 51,539 (Aug. 31, 1979) (drowsiness experienced in 10% of the placebo group and 6–7% of the dextromethorphan group).

Plaintiff's claims are therefore barred by Section 379r. The centerpiece of Plaintiff's lawsuit is the allegation that "Non-Drowsy DayQuil Products do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." Compl. ¶ 13; *see also id.* ¶¶ 2, 14, 16–17, 22. But the FDA expressly considered—and rejected—the contention that products containing dextromethorphan should disclose drowsiness as a possible side effect during its monograph process. Accordingly, "[i]f Plaintiffs were permitted to move forward with their claims, they would be using state law to impose labeling requirements on top of those already mandated in the FDCA and the regulations promulgated thereunder. . . . This is exactly what the FDCA does not permit." *Crichter*, 959 F.3d at 36; *see also Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011) ("The disclaimers that the plaintiff wants added to the labeling of the defendants' [product] are not identical to the labeling requirements imposed on such products by federal law, and so they are barred.").

Plaintiff attempts to avoid preemption by arguing that her claims are identical to federal requirements because the FDCA broadly prohibits "false or misleading" statements. *See* ECF No. 21 at 1 (Response to Pre-Motion letter). The Second Circuit rejected this exact argument in *Critcher*, holding that the FDCA's general prohibition on "false or misleading" statements cannot be used to circumvent preemption. 959 F.3d at 37–38 (interpreting analogous preemption provision for cosmetics). As the Court explained, the entire purpose of the FDCA's express preemption clause was to prevent states from imposing "*other* labeling requirements that have not been imposed by Congress or the FDA." *Id.* at 38. Accordingly, allowing states to impose

"*additional* labeling requirements" beyond a FDA final monograph would render Section 379r a nullity and "disrupt what Congress intended to be a uniform—and federally-led—regulatory scheme." *Id.*; *see also Bowling*, 65 F. Supp. 3d at 376–77 (rejecting argument that the FDCA's general "misbranding" provision can be used to avoid preemption); *Gorenstein v. Ocean Spray Cranberries, Inc.*, 2010 WL 10838229, at *1 (C.D. Cal. Jan. 29, 2010) (holding that, for analogous preemption provision for food labeling, allowing claim under the FDCA's general prohibition on "misbranding . . . would eviscerate the strict preemption requirements of" the statute).

Plaintiff fares no better with her assertion that the challenged phrase—non-drowsy—is not specifically mentioned in the FDA's final monograph. *See* ECF No. 21 at 1. "For plaintiffs to establish that their state law claims are not preempted, it is insufficient to show that the FDA has not permitted the label [non-drowsy]. Rather, plaintiffs would need to plead facts suggesting that the FDA has affirmatively *prohibited* the label." *Bowling*, 65 F. Supp. 3d at 376. Plaintiff cannot make that showing: the FDA expressly considered whether drowsiness is a side effect of dextromethorphan and imposed no prohibition against labeling DayQuil as "non-drowsy." "Because the [final monograph] does not require any specific disclaimers concerning" drowsiness, Plaintiff's "claims are preempted because she seeks to impose additional obligations on [P&G] not imposed by the [final monograph]." *Harris*, 538 F. Supp. 3d at 833; *see also Bimont*, 2015 WL 5256988, at *4 ("If, when determining whether state laws are within the scope of federal law, courts considered 'scope' to mean 'those areas that the FDA has already specifically regulated,' no tiling would be left of the word 'identical' in this context."); *PepsiCo*, 588 F. Supp. 2d at 538 (rejecting argument that "state requirements are permitted as long as the federal standard does not specifically address the terms or images at issue").[3]

[3] Plaintiff's reliance on *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312 (S.D.N.Y. 2017)

The FDA's treatment of *other* over-the-counter drugs further confirms that Plaintiff's claims are not identical to federal requirements. In contrast to dextromethorphan, the FDA has required a drowsiness disclosure for a wide range of active ingredients:

- Diphenhydramine. The monograph for antitussives requires products containing diphenhydramine to disclose that they "may cause marked drowsiness," 21 C.F.R. § 341.74(c)(4)(ix), after the FDA found that between 25% and 33.3% of study participants taking diphenhydramine experienced drowsiness. *See* 41 Fed. Reg. 52,536, 52,536 (Nov. 30, 1976); 44 Fed. Reg. 51,512, 51,524 (Aug. 31, 1979).[4]

- Antihistamines. The monograph for antihistamines requires certain active ingredients to disclose they "may cause drowsiness" or "may cause marked drowsiness," 21 C.F.R. § 341.72(c)(3), after the FDA found that 10% or more of participants in certain studies experienced drowsiness. *See* 50 Fed. Reg. 2,200, 2,210 (Jan. 15, 1985) (finding "10 to 20 percent of individuals" experienced drowsiness from chlorpheniramine maleate); 41 Fed. Reg. 38,312, 38,389 (Sept. 9, 1976) (finding 11% to 29% of individuals experienced drowsiness from pheniramine maleate); *id.* at 38,387 (advisory panel recommended a "may cause marked drowsiness" warning for methapyrilene because 11% of individuals experienced drowsiness).

- Antiemetics. The monograph for antiemetics requires several active ingredients to disclose they "may cause drowsiness" or "may cause marked drowsiness," 21 C.F.R. § 336.50(c)(6)–(7), after the FDA analyzed studies demonstrating drowsiness in a subset of consumers. 44 Fed. Reg. 41,064, 41,068 (July 13, 1979).

These examples confirm that the FDA will consider drowsiness as a potential side effect of over-the-counter drugs before issuing a final monograph. Thus, if Plaintiff were correct that "drowsiness is a common side effect" of dextromethorphan, the FDA would have required such a warning for DayQuil. The fact that FDA declined to do so confirms that manufacturers are

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is misplaced. *See* ECF No. 21 at 1. In *Canale*, the FDA monograph (relating to cavity prevention) had nothing to do with the challenged representations (relating to teeth whitening). Here, by contrast, the FDA specifically considered whether dextromethorphan and other antitussives cause drowsiness, and declined to require a drowsiness warning. *See supra* at 3–4.

[4] The FDA initially prohibited products containing diphenhydramine from being sold because "a drug causing this level of drowsiness is unacceptable, for reasons of safety, in a product for OTC use even with [a] warning statement." 41 Fed. Reg. 52,536, 52,536 (Nov. 30, 1976). Eventually, the FDA permitted antitussive products with diphenhydramine to be sold over-the-counter so long as they carried a drowsiness warning. *See* 59 Fed. Reg. 29,172 (June 3, 1994).

permitted to market products with dextromethorphan as "non-drowsy." *See Bowling*, 65 F. Supp. 3d at 376 (state law claims preempted because "the FDA has issued a monograph directly on point but declined, in spite of that, to indicate" that the challenged phrase "is misleading").[5]

Courts in this District have found state law claims preempted in analogous circumstances. In *Bowling*, the plaintiffs alleged that the phrase "restores enamel" on Listerine was misleading under state law, pointing to scientific evidence that "restoring enamel is physically impossible." 65 F. Supp. 3d at 373. Even though the FDA monograph was silent about the phrase "restores enamel," the court held that the plaintiffs' state law claims were preempted because the FDA monograph governing dental hygiene products did not "affirmatively *prohibit*[]" the phrase "restores enamel." *Id.* at 376. Similarly, in *Bimont*, the plaintiffs alleged that certain deodorants were misleading because they contained non-functional slack fill. 2015 WL 5256988, at *1. The court held that the state law claims were preempted because "[t]he FDA's failure to regulate in this area," when the FDA had done so in the food context, "constitutes strong evidence that the FDA considered the issue of slack-fill in drugs and cosmetics and decided that slack-fill in those products is insufficiently misleading to warrant regulation." *Id.* at *6.

The Court should reach the same conclusion here. The FDA considered whether to require drowsiness warnings for antitussives, did not require dextromethorphan to contain such a warning, and did not prohibit manufacturers from marketing products with dextromethorphan as non-

[5] Plaintiff oddly touts the example that "Dramamine contains an active ingredient that causes drowsiness, Dimenhydrinate," while "Dramamine also sells a 'less drowsy' version that contains a different active ingredient, Meclizine." Compl. ¶ 26. The statement "less drowsy" is fully consistent with the monograph for antiemetics. Products with dimenhydrinate are required to disclose that they "may cause *marked* drowsiness," while products with meclizine are only required to disclose that they "may cause drowsiness." 21 C.F.R. § 336.50(c)(6)–(7) (emphasis added). By contrast, manufacturers are not required to include any drowsiness warning for dextromethorphan.

drowsy. Plaintiff's claims therefore are preempted. *See Harris*, 538 F. Supp. 3d 833 (N.D. Ill. 2021) (state claims preempted under an FDA monograph); *Youngblood v. CVS Pharmacy*, 2021 WL 3700256, at *3 (C.D. Cal. Aug. 17, 2021) (state claims preempted because they differed from an FDA monograph).

II. Plaintiff Fails To Allege That DayQuil Labels Are Materially Misleading.

The Complaint should also be dismissed because it fails to plausibly allege that P&G made a false or misleading statement. Under New York law, all of Plaintiff's claims require allegations that a defendant made a false, misleading, or inaccurate statement.[6] A false or misleading statement is one that is "likely to mislead a reasonable consumer acting reasonably under the circumstances." *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); *see also Hesse v. Godiva Chocolatier, Inc.*, 463 F. Supp. 3d 453, 469 (S.D.N.Y. 2020) (similar for warranty claim). "It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer." *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013).

As shown below, Plaintiff fails to allege that P&G made a false or misleading statement because all of her allegations focus on dextromethorphan *in isolation*, which does not establish that DayQuil *as a whole* can cause drowsiness. Moreover, even when focusing on dextromethorphan alone, the sources cited in the Complaint do not plausibly show that dextromethorphan causes drowsiness in consumers.

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[6] *See Chufen Chen v. Dunkin' Brands, Inc.*, 954 F.3d 492, 500 (2d Cir. 2020) (GBL § 349 claim requires a "deceptive act[]"); *Goshen v. Mut. Life Ins. Co. of N.Y.*, 98 N.Y.2d 314, 324 n.1 (2002) ("The standard for recovery under [GBL] § 350, while specific to false advertising, is otherwise identical to section 349."); *Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 244 (S.D.N.Y. 2020) (warranty claims require "a material statement amounting to a warranty" and "breach of this warranty" (emphasis omitted)).

A. Plaintiff's allegations are defective because they do not address DayQuil.

All of Plaintiff's allegations focus on dextromethorphan in isolation. That matters, because DayQuil contains active ingredients other than dextromethorphan. For example, Plaintiff alleges that she took DayQuil Severe Cold & Flu, but that formulation contains four active ingredients: acetaminophen, dextromethorphan, guaifenesin, and phenylephrine. Liu Decl., Ex. B. There are no allegations in the Complaint suggesting that a product with the combination of these four ingredients causes drowsiness in consumers. In fact, the FDA has noted that one of the ingredients in DayQuil—phenylephrine, a nasal decongestant—can have a "mild central nervous system stimulation" at certain doses. 41 Fed. Reg. at 38,399.

Courts have dismissed lawsuits challenging statements that refer to the whole product when the underlying factual allegations relate solely to a particular ingredient. For example, in *In re GNC Corp.*, 789 F.3d 505 (4th Cir. 2015), the plaintiffs alleged that joint health supplements sold by GNC and Rite Aid were deceptively marketed because two ingredients—glucosamine and chondroitin—made the supplements ineffective. *Id.* at 510–11. The Fourth Circuit affirmed the dismissal of the misrepresentation claims because "the challenged representations—including 'supports improved joint health,' 'protects joints,' 'joint comfort,' and 'rebuilds cartilage'—refer to the products as a whole." *Id.* at 516. As the court explained, "Plaintiffs failed to allege that *all* of the purportedly active ingredients in each product are ineffective" and thus do not "adequately plead falsity of the representations regarding the products as a whole." *Id.*

So too here. Just as in *GNC*, Plaintiff's allegations focus on a single ingredient rather than the whole product. Because Plaintiff alleges no facts suggesting that DayQuil as a whole can cause drowsiness in consumers, the Complaint should be dismissed. *See Toback v. GNC Holdings, Inc.*, 2013 WL 5206103, at *5 (S.D. Fla. 2013) (allegations regarding the inefficacy of two ingredients do not plausibly suggest that the product "*as a whole* does not function as advertised" (emphasis

added)); *Eckler v. Wal-Mart Stores, Inc.*, 2012 WL 5382218, at *6 (S.D. Cal. Nov. 1, 2012) (dismissing false advertising claim because "none of these studies actually involved Equate" and "it is that overall formulation that's behind the representation at issue").

B. Plaintiff fails to allege that dextromethorphan causes drowsiness.

Even when focusing on dextromethorphan in isolation, Plaintiff fails to plead facts showing that the phrase "non-drowsy" would be misleading to a reasonable consumer. The sum total of Plaintiff's allegations relating to dextromethorphan appear in paragraphs 17–19 of the Complaint, but those allegations are woefully deficient.

Plaintiff places heavy weight on a single study from 1997 about the purported side effects of dextromethorphan (Compl. ¶ 17), but that study had nothing to do with DayQuil. Instead, the authors compared the rates of drowsiness for dextromethorphan and levodropropizine (another cough suppressant), and it was co-authored by a pharmaceutical company that produced levodropropizine. *See* Liu Decl., Ex. A at 2. Any conclusions drawn from the study are meaningless because, unlike the FDA's cited studies, the authors did not use a placebo group. *Compare* Liu Decl., Ex. A at 8 ("Lack of a placebo control group might represent a limitation of this trial."), *with* 44 Fed. Reg. at 51,539 (FDA noting studies indicating that drowsiness for dextromethorphan was less than placebo group); *see also Manuel v. Pepsi-Cola Co.*, 763 F. App'x 108, 109 (2d Cir. 2019) (rejecting studies to support a false advertising claim because "[n]one of the studies purports to establish a causal relationship . . . that is sufficiently strong").

Even accepting Plaintiff's characterization of the study, the reported results do not show that DayQuil is likely to cause drowsiness in consumers. The authors purport to find that 10% of patients who took dextromethorphan experienced drowsiness on a single day of a five day study, and the same patients experienced insignificant levels of drowsiness on the remaining four days. Liu Decl., Ex. A at 3, 7–8. Moreover, 3% of patients reported drowsiness even before taking

dextromethorphan, suggesting that any drowsiness could be attributable to other causes. *Id.* at 7. On that basis, the authors concluded that "*somnolence was reported for a low percentage of patients*" taking dextromethorphan. *Id.* at 2 (emphasis added). That finding is wholly consistent with the FDA's own conclusion that there is no "data demonstrating that . . . dextromethorphan . . . require[s] a drowsiness warning." 48 Fed. Reg. at 48,589.

Plaintiff fares no better with her one-sentence assertion that "[t]he FDA's adverse event report database confirms that 'sedation' is one of the most frequently-cited side-effects of dextromethorphan-containing products." Compl. ¶ 18. As an initial matter, it is unclear whether Plaintiff has a basis for that assertion: the FDA's database contains only *eight* reports of somnolence and *zero* reports of sedation for the active ingredients in DayQuil over the last twenty years. Liu Decl., Ex. C. By contrast, there were thirteen reports of insomnia over the same period. *Id.* Regardless, even if there had been adverse events reported for DayQuil, the FDA has explained that a report "does not mean that the drug or biologic caused the adverse event," "[t]here are many instances of duplicative reports," "[i]information in reports has not been verified," and "the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently."[7] These reports are therefore useless at the pleadings stage. *See Twohig v. Shop-Rite Supermarkets, Inc.*, 519 F. Supp. 3d 154, 164 (S.D.N.Y. 2021) (plaintiff's study did not support GBL claims because it was "sufficiently flawed that it does not contribute enough to render the claims plausible").

Nor can Plaintiff salvage her claims with the allegation that the FAA prohibits pilots from taking DayQuil before flying. *See* Compl. ¶ 19. Although the FAA guidance identifies DayQuil as a medication that should be avoided, the FAA does so because it mistakenly assumes that

[7] FDA Adverse Event Reporting System (FAERS) Public Dashboard, *supra* note 2.

DayQuil is a combination product that includes dextromethorphan and an antihistamine. *Id.* (FAA explaining that "[m]ost cough medications are safe for flight, but caution for combination products with sedating antihistamines"); *see also* 21 C.F.R. § 341.85(c)(4) (FDA monograph requiring combination products that include antitussives and antihistamines to disclose that they "may cause marked drowsiness"). The FAA is incorrect: DayQuil does not contain an antihistamine. *See* 21 C.F.R. § 341.12 (antihistamine active ingredients). In any event, even if the FAA had some reason to believe DayQuil caused drowsiness in pilots, that has no bearing on whether the statement "non-drowsy" is misleading to "a significant portion of the general consuming public or of targeted customers." *Jessani v. Monini N. Am., Inc.*, 744 F. App'x 18, 19 (2d Cir. 2018) (quotations omitted).

In sum, Plaintiff's own allegations fail to support the inference that dextromethorphan causes drowsiness in consumers. When, as here, materials cited "in the complaint contradict[] allegations in the complaint, the document[s] . . . control[], and the court need not accept the allegations in the complaint as true." *Mizel Roth IRA ex rel. Consol. Asset Funding 3 LP v. Unified Cap. Partners 3 LLC*, 2021 WL 1164439, at *1 (S.D.N.Y. Mar. 25, 2021) (quotations omitted). The Court should therefore dismiss Plaintiff's claims for failing to plausibly allege a false or misleading statement. *See Excevarria v. Dr Pepper Snapple Grp., Inc.*, 764 F. App'x 108, 109–10 (2d Cir. 2019) (affirming dismissal when "[n]one of the studies cited" supported mislabeling claim); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 141 (E.D.N.Y. 2015) (dismissing deception claims because cited studies did not raise the plausible inference that the label was false).

III. Plaintiff's Claims Should Be Dismissed For Additional Reasons.

In addition to the overarching defects identified above, Plaintiff's individual claims should be dismissed for several independent reasons.

A. The state consumer protection claims should be dismissed (Count 1).

Count 1 purports to assert misrepresentation claims under the consumer protection statutes of New York, five other states, and the District of Columbia. Compl. ¶ 41. In addition to the reasons identified above, the non-New York consumer protection claims should be dismissed for two additional reasons.

First, Plaintiff has not even attempted to allege how P&G violated the non-New York consumer protection statutes. Instead, she simply lists the other statutes that were supposedly violated. The Second Circuit has rejected this "laundry list" type of pleading approach, holding that state consumer protection claims should be dismissed when "[t]he complaint does little more than list a couple dozen state statutes in alphabetical order by state, without pleading any of their elements." *In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 163 (2d Cir. 2016); *see also In re Trilegiant Corp.*, 2014 WL 1315244, at *35 (D. Conn. Mar. 28, 2014) (dismissing state consumer protection claims where complaint "merely lists several other states' consumer protection statutes without explaining how those statutes relate to the Defendants' alleged conduct in this case"); *McGarvey v. Penske Auto. Grp.*, 639 F. Supp. 2d 450, 465 (D.N.J. 2009) (similar), *modified on other grounds*, 2010 WL 1379967 (D.N.J. Mar. 29, 2010).

Second, Plaintiff, a New York resident, lacks statutory standing to advance claims under non-New York consumer protection statutes. "For statutory standing, the question is whether the plaintiff has a cause of action under the statute." *Robainas v. Metro. Life Ins. Co.*, 2015 WL 5918200, at *5 (S.D.N.Y. Oct. 9, 2015) (quotations omitted). Here, each of the consumer protection statutes invoked in Count 1 confer statutory standing only to residents, persons who are injured within the State, or persons who suffer injuries that are otherwise closely connected to the State. *See Chavez v. Wal-Mart Stores, Inc.*, 2014 WL 12591252, at *3–5 (C.D. Cal. Jun. 2, 2014) (District of Columbia, Missouri, New York, Rhode Island, and Washington); Mass. Gen. Laws ch.

93A, § 1(b) (Massachusetts); *MyWebGrocer, Inc. v. Adlife Mktg. & Commc'ns Co.*, 383 F. Supp. 3d 307, 313 (D. Vt. 2019) (Vermont).

Plaintiff fails to show that *she* has statutory standing under the non-New York consumer protection laws asserted in the Complaint. Plaintiff is a citizen of New York and purchased the product in New York. Compl. ¶¶ 5, 28. Because she cannot establish that she suffered an injury outside of New York, she cannot pursue non-New York statutory claims. To hold otherwise "would allow Plaintiff to engage in lengthy and expensive discovery with respect to alleged violations of state laws when the Court cannot be certain that any individual suffered an injury under those laws." *In re HSBC Bank, USA, N.A., Debit Card Overdraft Fee Litig.*, 1 F. Supp. 3d 34, 49–50 (E.D.N.Y. 2014).[8]

B. The New York GBL claims should be dismissed (Counts 2 & 3).

To assert a claim under New York's GBL for deceptive trade practices (GBL § 349) or false advertising (GBL § 350), Plaintiff must show that P&G's actions (1) were consumer-oriented, (2) materially misleading, and that they (3) caused injury to the Plaintiff. *See Chufen Chen v. Dunkin' Brands, Inc.*, 954 F.3d 492, 500 (2d Cir. 2020). As explained above, the GBL claims should be dismissed because they are preempted and Plaintiff fails to allege a false or misleading statement. Plaintiff's GBL claims also fail for two additional reasons.

[8] The Second Circuit's decision in *Langan v. Johnson & Johnson Consumer Co.*, 897 F.3d 88 (2d Cir. 2018), which considered whether the plaintiff had *constitutional (Article III) standing* to bring a class-action claim on behalf of out-of-state consumers, has no bearing on this *statutory standing* question. As another judge in this District has explained, "[n]othing in *Langan* . . . precludes a defendant from moving to dismiss a CAFA plaintiff's claims under a particular statute pursuant to Rule 12(b)(6), on the grounds that the plaintiff fails to state a claim for its own account—a question entirely different from whether it has constitutional standing." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, 2018 WL 7197233, at *21 (S.D.N.Y. Dec. 26, 2018).

First, Plaintiff's claims are barred by the GBL's "safe harbor" clauses, which provide a "complete defense" to claims challenging advertising that is "subject to and complies with the rules and regulations" of any federal agency. N.Y. Gen. Bus. L. §§ 349(d); 350-d. Because the label for DayQuil complies with the FDA's final monograph, Plaintiff's claims fall squarely within the safe harbor. *See Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) (compliance with FDA regulations governing over-the-counter warning requirements was a "complete defense" to GBL claims); *Flagg v. Yonkers S&L Ass'n*, 307 F. Supp. 2d 565, 581 n.19 (S.D.N.Y. 2004) (similar).

Second, Plaintiff fails to satisfy the "actual injury" element of her GBL claims. The Complaint asserts two purported theories of injury: (i) Plaintiff "would not have bought the DayQuil Product" absent the alleged misrepresentation and therefore "did not get what [she] paid for," Compl. ¶¶ 28, 54, and (ii) Plaintiff paid a "price premium" for DayQuil "due to Defendant's misrepresentations," *id.* ¶ 63. Neither theory is sufficient.

As to the first theory, New York courts have rejected the idea that "consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury under General Business Law § 349." *Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 56, (1999). Although Plaintiff seeks a full refund for her purchase, it is "well-settled" that a consumer "whose purchase was allegedly procured through deception" cannot recover "a refund of the price" under the GBL. *Dash v. Seagate Tech. (U.S.) Holdings, Inc.*, 27 F. Supp. 3d 357, 361 (E.D.N.Y. 2014); *see also Rodriguez v. It's Just Lunch Int'l,* 2018 WL 3733944, at *5 (S.D.N.Y. 2018) (in GBL case, "[a] full refund is not . . . a tenable model of damages under the benefit-of-the-bargain rule"). This is because "deceived consumers may nevertheless receive—and retain the benefits of—something of value, even if it is not precisely what they

believed they were buying." *Dash*, 27 F. Supp. 3d at 361–62; *Baron v. Pfizer, Inc.*, 840 N.Y.S.2d 445, 448 (App. Div. 2007) (plaintiff's allegation that she would not have purchased the product absent deceptive practices did not state a "cognizable injury").

As to the second theory, a plaintiff alleging a price premium theory must do more than "recite the word 'premium' multiple times in [her] Complaint." *Izquierdo v. Mondelez Int'l, Inc.*, 2016 WL 6459832, at *7 (S.D.N.Y. Oct. 26, 2016). Here, however, the Complaint offers little more than the conclusory assertion that P&G charges a "price premium" for DayQuil over other cold and cough medications that are not marketed as "non-drowsy." Moreover, the Complaint cites NyQuil as a comparable cold and cough medication marketed by P&G that is not labeled as "non-drowsy," and that product costs the exact same amount as DayQuil.[9] The GBL claims should therefore be dismissed because Plaintiff does not allege that she "paid a *higher* price for [DayQuil] than [she] otherwise would have, absent deceptive acts." *Izquierdo*, 2016 WL 6459832, at *7.

C. The express warranty claim should be dismissed (Count 4).

To state an express warranty claim under New York law, Plaintiff must allege that (1) P&G made a material statement amounting to a warranty; (2) Plaintiff relied on this warranty "as a basis" for purchasing P&G's products; (3) P&G breached this warranty; and (4) the breach injured Plaintiff. *Lugones v. Pete & Gerry's Organic, LLC*, 440 F. Supp. 3d 226, 244 (S.D.N.Y. 2020). As explained above, Plaintiff's warranty claim should be dismissed because it is preempted and because there are no plausible allegations that P&G made any false or misleading statements. It should also be dismissed because "[u]nder New York law, breach of warranty damages are usually

[9] *See* https://www.cvs.com/shop/vicks-nyquil-cold-flu-nighttime-relief-liquicaps-24-count-24-pack-prodid-1011902 (noting that NyQuil Cold & Flu 16 count pack costs $9.99); https://www.cvs.com/shop/vicks-dayquil-cold-flu-multi-symptom-relief-liquicaps-prodid-1011963 (noting that DayQuil Cold & Flu 16 count pack costs $9.99).

measured by the benefit-of-the-bargain rule," *Bennett v. United States Tr. Co*., 770 F.2d 308, 316 (2d Cir. 1985), and Plaintiff fails to allege that she paid any price premium. *Supra* at 22.

The express warranty claim should be dismissed for yet another reason: Plaintiff failed to provide timely notice, which is a "condition precedent" to any breach of warranty claim. *Lugones*, 440 F. Supp. 3d at 244–45. New York law requires a buyer, "within a reasonable time after he discovers or should have discovered any breach," to "notify the seller of breach or be barred from any remedy." N.Y. U.C.C. § 2-607(3)(a). "Whether notice is sufficient and timely is typically measured by the purpose for requiring notice." *Besicorp Grp., Inc. v. Thermo Electron Corp.*, 981 F. Supp. 86, 101 (N.D.N.Y. 1997). "The primary reason for requiring notice is to give the seller the opportunity to make adjustments or replacements, opportunities to minimize the buyer's loss and reduce the seller's own liability." *Singleton v. Fifth Generation, Inc.*, 2016 WL 406295, at *12 (N.D.N.Y. Jan. 12, 2016).

Plaintiff did not do so here. Plaintiff's purported pre-suit notice was sent by certified mail on December 23, 2021, just six days before the Complaint was filed. Even assuming that P&G received this letter the next business day, P&G was not provided "a reasonable time" to cure any breach before Plaintiff filed suit just two business days later. *Singleton*, 2016 WL 406295, at *12. Plaintiff thus is barred from pursuing breach-of-warranty claims. *See also Barton v. Pret A Manger (USA) Ltd.*, 535 F. Supp. 3d 225, 246 (S.D.N.Y. 2021) (dismissing warranty claims for failure to allege pre-suit notice and citing nine New York cases that did the same).

D. The Magnuson-Moss Warranty Act claim should be dismissed (Count 5).

The MMWA requires the plaintiff to "adequately plead a cause of action for breach of written or implied warranty under state law." *Budhani v. Monster Energy Co.*, 527 F. Supp. 3d 667, 686 (S.D.N.Y. 2021). As noted above, however, Plaintiff's state-law warranty claim should

be dismissed because it is preempted and because there are no plausible allegations that P&G breached any warranty. The MMWA claim fails for the same reasons.

The MMWA claim is defective for three additional reasons.

First, the challenged representation is not a covered "warranty" as defined in the MMWA. The MMWA defines "warranty" as a "written affirmation" that a consumer product will be "defect free or will meet a specified level of performance over a specified period of time." 15 U.S.C. § 2301(6). The representation "non-drowsy" is a description of the product, not an affirmation that it will be defect free or meet some specified level of performance. *See, e.g.*, *Bowling*, 65 F. Supp. 3d at 378 (dismissing MMWA claim because representation "Restores Enamel" on label was product description, not a warranty).

Second, the MMWA does not apply to warranties that are permitted by the FDCA. The MMWA is "inapplicable to any written warranty the making or content of which is otherwise governed by Federal law." 15 U.S.C. § 2311(d). Here, as noted above, the FDA's final monograph for antitussives allows P&G to label DayQuil as "non-drowsy." *Supra* at 7–14. Accordingly, Plaintiff is barred from bringing a MMWA claim. *See Hernandez v. Johnson & Johnson Consumer Inc.*, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020) (dismissing MMWA claim challenging drug label because the FDCA comprehensively regulates labels for over-the-counter drugs); *Mahoney v. Endo Health Sols., Inc.*, 2016 WL 3951185, at *8 (S.D.N.Y. July 20, 2016) (dismissing MMWA claim because product was governed by FDCA).

Third, Plaintiff cannot satisfy the $25 amount-in-controversy threshold for MMWA claims. Under the statute, "[n]o claim shall be cognizable . . . if the amount in controversy of any individual claim is less than the sum or value of $25." 15 U.S.C. § 2310(d)(3)(A). Plaintiff does not allege she paid more than $25 for her purchase of DayQuil (nor could she). She is therefore statutorily

barred from asserting a claim under the MMWA. *See Trisvan v. Regal Ent. Grp.*, 2021 WL 620981, at *4 (E.D.N.Y. Feb. 17, 2021) (dismissing MMWA claim when plaintiff did not meet amount-in-controversy requirement); *Ebin v. Kangadas Food Inc.*, 2013 WL 3936193, at *1 (S.D.N.Y. July 26, 2013) (similar and rejecting argument that CAFA jurisdiction allows a plaintiff to avoid the amount-in-controversy requirement).

IV. Plaintiff Lacks Standing To Seek Injunctive Relief.

To have standing to seek an injunction, Plaintiff must allege "a sufficient likelihood that [she] will again be wronged in a similar way." *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983). That harm must be "actual or imminent" rather than "conjectural" or "hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quotations omitted).

Plaintiff cannot meet that standard. Although Plaintiff baldly asserts that she would purchase DayQuil again without the purportedly misleading statement (Compl. ¶ 29), the Second Circuit has rejected that desire as sufficient to confer standing to seek injunctive relief. *Berni v. Barilla S.P.A.*, 964 F.3d 141 (2d Cir. 2020). As *Berni* explained, "past purchasers of a product . . . are not likely to encounter future harm of the kind that makes injunctive relief appropriate" because they have full knowledge of the supposed misrepresentation. *Id.* at 147. For the same reason here, Plaintiff's claim for injunctive relief should be dismissed. *See Campbell v. Whole Foods Mkt. Grp., Inc.*, 516 F. Supp. 3d 370, 395 (S.D.N.Y. 2021) (rejecting allegation that plaintiff "intends to, seeks to, and will purchase the Product again" as sufficient to confer standing to seek injunctive relief); *Duran v. Henkel of Am., Inc.*, 450 F. Supp. 3d 337, 356 (S.D.N.Y. 2020) (plaintiff who merely alleges that she "would purchase a product if re-engineered or re-marketed does not show a real or immediate threat of future injury").

CONCLUSION

This Court should grant P&G's motion and dismiss the Complaint with prejudice.

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